

K021690

OCT 24 2002

510(k) NOTIFICATION SUMMARY (Per 21 CFR 807.92)

Prepared: 20 May 2002

TRADE NAME: PAH-M3+1 Hyperbaric Chamber System

COMMON NAME OF DEVICE: Multiplace Hyperbaric Chamber

CLASSIFICATION: 73 CBF, 21 CFR 868.5470

ESTABLISHMENT REGISTRATION NUMBER: Pending

CLAIMED PREDICATE DEVICE(S):

Perry Sigma II Hyperbaric Chamber – K862198
Perry Sigma Plus/II Hyperbaric Chamber – K983648

ADDRESS OF MANUFACTURER: Pan-America Hyperbarics, Inc.
No.9, Lane 12, Guang Feng 1st Street
Ba-de City, Tao Yuan County
Taiwan, R.O.C.
+886-3-3676676

CONTACT PERSON: Cheng, Kuo-Chung

EXECUTIVE SUMMARY

The PAH-M3+1 Hyperbaric Chamber System is a Class A multiplace hyperbaric chamber designed to treat up to 4 patients at up to a maximum operating pressure of 3 Atmospheres Absolute (ATA) or 29.4 pounds per square inch gauge (psig). The chamber uses compressed air as the pressurization gas and 100% oxygen as the hyperbaric treatment gas.

The PAH-M3+1 Hyperbaric Chamber System is intended to be procured and used by physicians to treat a variety of medical conditions that respond to hyperbaric oxygen. The Undersea & Hyperbaric Medical Society (UHMS) produces a list of medical conditions that have been identified for the appropriate primary or adjunctive use of hyperbaric oxygen. These approved conditions include: air or gas embolism; carbon monoxide poisoning and smoke inhalation; clostridial myonecrosis (gas gangrene); crush injury, compartment syndrome and other acute traumatic ischemias; decompression sickness; enhanced healing of selected problem wounds; exceptional blood loss anemia; necrotizing soft tissue infections; osteomyelitis (refractory); radiation tissue damage (osteoradionecrosis); compromised skin flaps and grafts; thermal burns; and, intracranial abscess. Aggressive research into the beneficial effects of hyperbaric oxygen, when appropriately applied, will result in additional medical conditions being added to the list of indications by the UHMS.

The PAH-M3+1 Hyperbaric Chamber System is designed and fabricated in accordance with the requirements of the ANSI/ASME Boiler and Pressure Vessel Code, Section VIII, Division 1, Pressure Vessels; ANSI/ASME-PVHO-1 (American Society of Mechanical Engineers-Pressure Vessels for Human Occupancy); and, NFPA 99, Health Care Facilities, Chapter 19, Hyperbaric Facilities (Chapter 20, 2002 Edition). The overall external length of the chamber is 4500mm (approx. 14.76 ft). Its internal diameter is 1016mm (approx. 40 inches). There are two compartments: main compartment and transfer compartment. Three (3) removable seats and one fixed (1) seat are installed in main compartment and transfer compartment respectively. Two independent fire suppression systems, water deluge system and handline system, are installed in accordance with the requirements of NFPA 99, Chapter 19 (Chapter 20, 2002 Edition). Pressurization is provided by compressed air with 100% oxygen administered to the patient by using properly fitting oronasal masks or head tents. A low-voltage patient intercommunication system designed and installed in accordance with NFPA 99, Chapter 19 (Chapter 20, 2002 Edition) and provides communications between the patients in the chamber and the outside chamber operator. A Teledyne TED-191 oxygen analyzer is installed to monitor the concentration of oxygen inside the chamber continually. The system consists of an operator control console that contains all of the controls and connection points. Single operator chamber pressure control is achieved via a simple manual pneumatic control. A penetrator plate is provided in the vessel wall to allow user supplied medical monitoring leads, etc., to be used as required. The patients are loaded and unloaded by a retractable gurney, which is equipped with a sliding transport chair. When supine position is needed, a sliding bunk will be used instead. The chamber is also equipped with safety switch for pressurization. There is no gas supply before the chamber's door is closed and secured thoroughly.

Intended Use:

It is the expressed, intended use of the Pan-America Hyperbarics' PAH-M3+1 Hyperbaric Chamber System to provide therapy to those patients with selected medical conditions that have been determined to respond to the application of hyperbaric oxygen. As a Class II prescriptive device, it is further intended for physician involvement in its procurement and routine use.

The UHMS is the professional medical organization chartered with setting the standards of care defining the appropriate use of hyperbaric oxygen. More specifically, the UHMS publishes a listing of medical conditions that have been clearly established as appropriate primary or adjunctive use of hyperbaric oxygen (HBO). The disorders on the list have been scientifically validated and verified through extensive data collection. It should be noted that the list is dynamic. Based on the strength of the scientific data, disorders are both added and removed from the list, depending on the outcomes of scientific pursuit.

The conditions listed as appropriate for the use of HBO in the current edition of the Hyperbaric Oxygen Therapy Committee Report (1999) are as follows:

1. Air or gas embolism
2. Carbon monoxide poisoning and carbon monoxide poisoning complicated by cyanide poisoning
3. Clostridial myositis and myonecrosis
4. Crush injury, compartment syndrome, and other acute traumatic ischemias
5. Decompression sickness
6. Enhanced of selected problem wounds
7. Exceptional blood loss anemia
8. Necrotizing soft tissue infections
9. Osteomyelitis (refractory)
10. Delayed radiation injury (soft tissue and bony necrosis)
11. Skin grafts and flaps (compromised)

12. Thermal burns
13. Intracranial abscess

The Pan-America Hyperbarics' PAH-M3+1 Hyperbaric Chamber System is designed to be installed and operated in medical facilities as defined by the NFPA 99, Health Care Facilities, Chapter 19, Hyperbaric Facilities (Chapter 20, 2002 Edition). Further, this system is intended to be operated only by medical personnel specifically trained in the appropriate use of HBO and the safe operations of all related equipment such as the hyperbaric chamber.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 2002

Pan-America Hyperbarics, Incorporated
C/O Mr. W. T. Workman
Workman Hyperbaric Services, Incorporated
18111 Copper Ridge Drive
San Antonio, Texas 78259-3612

Re: K021690

Trade/Device Name: Hyperbaric Chamber System, Model PAH-M3+1
Regulation Number: 868.5470
Regulation Name: Hyperbaric Chamber
Regulatory Class: II
Product Code: CBF
Dated: September 5, 2002
Received: September 6, 2002

Dear Mr. Workman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

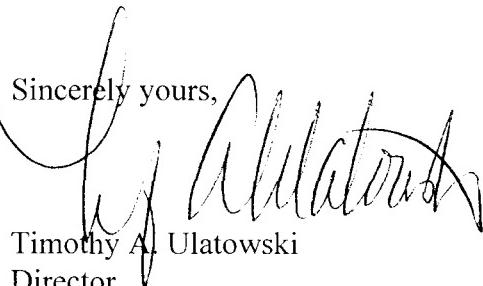
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,


Timothy A. Ulatowski
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021690

Device Name: Pan-America Hyperbarics, Inc., PAH-M3+1 Hyperbaric Chamber System

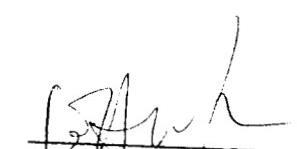
Indications for Use:

The conditions listed as appropriate for the use of HBO in the current edition of the Hyperbaric Oxygen Therapy Committee Report (1999) are as follows:

1. Air or gas embolism
2. Carbon monoxide poisoning and carbon monoxide poisoning complicated by cyanide poisoning
3. Clostridial myositis and myonecrosis
4. Crush injury, compartment syndrome, and other acute traumatic ischemias
5. Decompression sickness
6. Enhanced healing of selected problem wounds
7. Exceptional blood loss anemia
8. Necrotizing soft tissue infections
9. Osteomyelitis (refractory)
10. Delayed radiation injury (soft tissue and bony necrosis)
11. Skin grafts and flaps (compromised)
12. Thermal burns
13. Intracranial abscess

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

(Optional Format 3-10-98)

510(k) Number: K021690